UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

DEFENDANTS' AMENDED MOTION TO EXCLUDE
SUPPLEMENTAL DECLARATION OF THOMAS G. McGUIRE

On October 8, 2014, class plaintiffs served a "Supplemental Declaration of Thomas G. McGuire," which opines on the purported date to which AstraZeneca and Ranbaxy would have agreed for the entry of generic Nexium in the absence of any alleged reverse payment to Ranbaxy.[1] This untimely supplemental report should be excluded for three reasons.

First, the question of what licensed entry date Ranbaxy and AstraZeneca purportedly would have agreed to absent the alleged reverse payment is irrelevant to the sole theory of liability that remains in the case. As the Court stated at the final pretrial conference, this Court has already ruled as matter of law that the settlement agreement between AstraZeneca and Ranbaxy "had no antitrust impact because Ranbaxy could never get on the market." Hearing Tr., Sept. 30, 2014, at 4. Accordingly, even under plaintiffs' conspiracy claim, the only theory of antitrust impact that remains in the case is that the Teva settlement caused antitrust impact. Because Dr. McGuire's new report does not address what date Teva and AstraZeneca allegedly would have agreed to, and focuses solely on the Ranbaxy licensed entry date that this Court has already ruled did not cause any cognizable antitrust impact, it has no probative value and will not assist the jury in deciding any issues germane to this liability trial.

[1] Plaintiffs evidently intend to offer this new expert opinion when Dr. McGuire is recalled at the end of their case, which they currently estimate to occur on November 13.

Second, Dr. McGuire's expert report is beyond untimely. Expert discovery closed over a year ago. The report is based on facts—what happened with AstraZeneca's stock price after the Ranbaxy settlement in 2008—that have been available for years. Plaintiffs should not be permitted to come forward with an entirely new expert opinion two weeks before the start of trial based on factual data that, if relevant at all, was readily available prior to the applicable expert disclosure deadlines. Otherwise, every litigant would be incentivized to hold back key portions of its expert opinions until the eve of trial.

Third, and in any event, Dr. McGuire's proposed new opinion does not satisfy Rule 702. To say that Dr. McGuire's methods flunk *Daubert* and *Kumho Tire* is to understate the matter considerably. His analysis—using a purported stock market price "event study" to calculate an increase in AstraZeneca's market capitalization and then reverse-engineering a supposed "competitive" entry date for Ranbaxy—is everything Rule 702 seeks to prevent: new not only to the litigation context, but to the world beyond the courtroom; untested; non-peer-reviewed; and implemented by a witness with no expertise whatsoever in the methodology. And by waiting until the eve of trial and long after the close of expert discovery to foist this novel and highly specious opinion upon defendants, plaintiffs have insulated it from being tested by discovery, deposition, and properly briefed motions to exclude.

The Court should put an end to plaintiffs' continuing efforts to sandbag defendants with new, irrelevant and ever more speculative last-minute theories. The supplemental report, and the opinions contained therein, should be excluded.

ARGUMENT

I. McGUIRE'S NEW OPINIONS ARE IRRELEVANT IN LIGHT OF THE COURT'S RULINGS.

If it were not already clear to plaintiffs, the Court stated at the final pretrial conference that it has ruled as a matter of law that the settlement agreement between AstraZeneca and Ranbaxy "had no antitrust impact because Ranbaxy could never get on the market." Hearing Tr., Sept. 30, 2014, at 4. And there was nothing unclear about the Court's September 4 ruling that "the Ranbaxy settlement is not a basis for imposing antitrust liability." Dkt. No. 977, at 101. The Court has rejected Plaintiffs' theory that the AstraZeneca/Ranbaxy agreement somehow delayed Teva's market entry. Hearing Tr., Sept. 30, 2014, at 5. And the Court has made clear that "[t]he resulting effect of the Court's rulings . . . is that Plaintiffs may pursue at trial antitrust claims based on the *Teva* settlement." Dkt. No. 977, at 129 (emphasis added).

Despite the Court's rulings and admonitions, Plaintiffs' new October 8 "supplemental" McGuire declaration addresses only the AstraZeneca/*Ranbaxy* settlement, opining—contrary to each of the numerous positions on entry date plaintiffs and their experts had previously taken—that AstraZeneca and Ranbaxy "would have agreed to a date for generic entry of in or around January 2011" in a settlement without "unlawful reverse payments." Ex. 1 (10/8/14 McGuire Supplemental Report) ¶ 4.

The subject matter of this supplemental opinion is irrelevant to the only theory of liability that remains in the case, which must be based on the *Teva* settlement. The Court was clear at the pretrial conference that "we're not going back at the trial to redo things done by summary judgment." Hearing Tr., Sept. 30, 2014, at 4. Because the Court has ruled that Ranbaxy could not have entered the market before May 27, 2014 regardless of whatever entry date AstraZeneca and Ranbaxy allegedly might have agreed to in a "but for" world, the proposed supplemental

opinion of Dr. McGuire is irrelevant to the limited issues remaining for trial. Expert testimony that does not relate to any issue in the case "is not relevant and, ergo, non-helpful."[2] Dr. McGuire's new report should be excluded on that basis alone.

II. McGUIRE'S NEW OPINION IS UNTIMELY AND PREJUDICIAL.

Dr. McGuire's report, served on October 8, less than two weeks before the start of trial, is patently untimely. Dr. McGuire does not base his new opinion on any information unavailable to him at the time of his original expert report—AstraZeneca's stock price during the pertinent period has been a matter of public record for six and a half years. Rather, he simply purports to change wholesale his methodology for determining a "but-for" Ranbaxy entry date, arriving at an entirely new date never before disclosed in this litigation.

Anticipating this objection to his report, Dr. McGuire blithely states that "[t]his report supplements the interpretation of the event study conducted in my original report," Ex. 1 ¶ 2, as if his new opinion merely updates some earlier opinion on the same topic. That claim is disingenuous at best: The "event study" to which Dr. McGuire refers did *not* pertain to a calculation of the supposedly "competitive" entry date for Ranbaxy. Ex. 2 (8/23/13 McGuire Report) at ¶¶ 151-157 & Attachment D ¶¶ 20-34. Nowhere in any of Dr. McGuire's *four* previous expert reports did he suggest an "event study" could be used for such a purpose, much less did he purport to use one in that manner.

Dr. McGuire and plaintiffs offer no excuse for offering entirely new opinions at this late date that directly contradict their prior positions. Defendants deposed Dr. McGuire based on the opinions expressed in his two original reports and prepared their defense accordingly.

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2 *McGovern ex rel. McGovern v. Brigham & Women's Hospital*, 584 F. Supp. 2d 418, 422 (D. Mass. 2008) (quoting 3 J. Weinstein M. Berger, *Weinstein's Evidence* ¶ 702[02], pp. 702-18 (1988)).

Defendants had no opportunity to depose Dr. McGuire regarding his new October 2014 opinions, nor were they able to address this new opinion when it was served, mere days before trial and nearly a year after the close of expert discovery. The Court should exclude this untimely and prejudicial last-minute opinion and spare Defendants the time and expense of securing an additional expert opinion to respond to McGuire's out-of-time submission.[3]

III. McGUIRE'S NEW OPINION IS SPECULATIVE AND UNRELIABLE.

Although defendants have not been able to depose Dr. McGuire regarding his new opinion, it is nevertheless clear his methodology cannot possibly meet the standards of Rule 702. Dr. McGuire's analysis purports to divine the so-called Ranbaxy competitive entry date by assuming that the increase in AstraZeneca's market capitalization on the day of the announcement of the settlement is precisely equal to the future value of supposedly anticompetitive profits realized from the Ranbaxy settlement; and then calculating the number of days of discounted gross profits attributable to Nexium that would be required to increase AstraZeneca's valuation by that amount. This analysis suffers from numerous obvious flaws.

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[3] *See Brincku v. Nat'l Gypsum Co.*, 518 Fed. App'x 776 (11th Cir. 2013) (district court did not abuse its discretion "by striking a new and untimely report from one of Plaintiffs' originally designated expert witnesses … where the report containing the untimely opinion directly contradicted the expert's earlier sworn testimony"); *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 680-81 (6th Cir. 2011) (district court did not abuse its discretion in striking expert's supplemental declaration where it was "contradictory to [his] previous specific-causation opinion, and reliant upon a new differential-diagnosis methodology that [the expert] failed to discuss within the permissible time frame for filing expert reports"); *In re Ready-Mixed Concrete Antitrust Litig.*, 261 F.R.D. 154, 158-60 (S.D. Ind. 2009) (excluding "supplemental" expert opinions, because Rule 26 "does not give license to sandbag one's opponent with claims and issues which should have been included in the expert witness' report"); *Gallagher v. S. Source Packaging, LLC*, 568 F. Supp. 2d 624, 631 (E.D.N.C. 2008) (excluding new expert report where party did not file new expert report to correct an inadvertent error or omission, but instead to address numerous problems with the report discussed in plaintiffs' motion for summary judgment); *Gilbane Bldg. Co. v. Downers Grove Community High Sch. Dist. No. 99*, No. 02 C 2260, 2005 WL 838679, at *8 (N.D. Ill. Apr. 5, 2005) (excluding new report that "significantly expand[ed]" upon original report).

First, and most fundamentally, it is without any academic or scientific foundation whatsoever. Although an event study is "an accepted method of measuring the impact of alleged securities fraud on a stock price and . . . proving loss causation and damages in a securities fraud case,"[4] there is absolutely no scientific basis for using one to divine the licensed entry date that two litigants in a patent infringement case would agree to in a settlement agreement without an alleged reverse payment. This methodology is purely a litigation-based creation of Dr. McGuire, who relies solely upon his own unpublished working paper—written during the pendency of this litigation and never previously disclosed to defendants—as support for its use. Ex. 1 at 2 n.3.[5] It has not been tested, peer-reviewed or otherwise demonstrated to be reliable in any way.[6]

Second, even if this opinion otherwise met the standards of Rule 702, Dr. McGuire would be unqualified to render it. Dr. McGuire is a health economist, not an expert in securities or finance. Ex. 4 (11/25/13 McGuire Dep.) at 13:15-14:21. Defendants are therefore presumably on safe ground stating that Dr. McGuire lacks the requisite expertise and experience to offer this opinion. Of course, because Plaintiffs waited until the eve of trial to serve this

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4 *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse First Boston*, 853 F. Supp. 2d 181, 186 (D. Mass. 2012), *aff'd sub nom Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Securities (USA) LLC*, 752 F.3d 82 (1st Cir. 2014).

5 Moreover, this July 2014 unpublished paper does not even support Dr. McGuire's conclusions here. To the contrary, his analysis of settlements involving drugs that represent over 10% of the companies' revenues (Nexium accounted for 16% of AstraZeneca's revenues in 2008) demonstrates ***no difference at all*** in stock price reaction between settlements that do and do not involve reverse payments. Ex. 3 (NBER Working Paper) at 27-28.

6 *See, e.g.*, *Bricklayers & Trowel Trades Int'l Pension Fund v. Credit Suisse Securities (USA) LLC*, 752 F.3d 82 (1st Cir. 2014) (court considering whether expert testimony is reliable should consider "(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline" (quoting *United States v. Mooney*, 315 F.3d 54, 62 (1st Cir.2002))); *U.S. v. Giambro*, 544 F.3d 26, 33 (1st Cir. 2008) (affirming district court's exclusion of expert because analyses "were untested and lacked peer-review," and expert "failed to provide the known or potential rate of error for his statistical analysis").

opinion, defendants have had no opportunity to probe into precisely the extent of Dr. McGuire's expertise and experience *vel non* in using event studies for *any* non-litigation purpose, much less an attenuated and entirely untested one such as predicting the supposedly "competitive" entry date for a generic drug.[7] However, Dr. McGuire's new expert report reveals no prior experience with these sorts of event study analyses.

Third, the fact that Dr. McGuire's latest stab at divining a but-for entry date for Ranbaxy is inconsistent with his own prior opinion and the plaintiffs' representations to the Court demonstrates the inherently speculative nature of his project. Dr. McGuire initially opined that a "competitive, negotiated" entry date for Ranbaxy was between "December 2008" and "September 2010." Ex. 2 at 74. Now, on the eve of trial, Dr. McGuire discards that opinion and instead opines that AstraZeneca would have agreed to a January 2011 entry date for generic Nexium in the "but for" world. Ex. 1 at 2. His new opinion also contradicts Plaintiffs' counsel, who represented to the Court that the "but for" agreed entry date for Ranbaxy would have been May 2012. Dkt. No. 868, at 9. When experts offer contradictory and inconsistent opinions, it is evident that they are engaged in rank speculation and that their opinions should be excluded.[8]

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7 *See, e.g.*, *Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 486 (1st Cir. 2010) (court should consider "whether the testimony was prepared for the purpose of the litigation or whether it was something that the expert did in her ordinary practice"); *Ambit Corp. v. Delta Airlines, Inc.*, 707 F. Supp. 2d 74, 76-77 (D. Mass. 2010) (whether expert is qualified to testify regarding topic "turns on whether our society—outside the litigation process itself—turns to this individual to render the opinion sought to be presented in court").

8 *See McIlroy v. Comm'r of Social Sec.*, 42 Fed. App'x 738 (6th Cir. 2002) (affirming ALJ's rejection of expert opinion because, *inter alia*, it contradicted expert's own previous findings); *Solaia Tech. LLC v. ArvinMeritor, Inc.*, 361 F. Supp. 2d 797, 807-11 (N.D. Ill. 2005) (striking portions of supplemental expert affidavit that contradicted expert's prior sworn testimony); *Gallagher v. Source Packaging, LLC,* 568 F. Supp. 2d 624, 635 (E.D.N.C. 2008) (expert opinion that "changes to reflect whatever position [the party] is currently taking as to lost revenue . . . is patently unreliable"); *Council 31 v. Ward*, No. 87 C 356, 1995 WL 549022, at *1 (N.D. Ill. Sept. 12, 1995) (rejecting plaintiffs' new expert reports, which were substantially different from the earlier reports, used different data and analysis, and changed the theory of the case); *Beller ex*

Fourth, Dr. McGuire's analysis rests upon multiple faulty assumptions that are never explained, supported or justified.[9] To take just a few examples:

- Dr. McGuire simply assumes AstraZeneca's market valuation would not increase as a result of a "competitive" settlement, and therefore that any increase in market capitalization must be due to supposedly anticompetitive effects of the agreement. It thus assumes that, other factors being equal, the settlement of major litigation involving a significant product would do absolutely nothing to assuage risk-averse investors or enhance investor confidence in a company no longer laboring under the cloud of litigation. It also assumes the settlement of major litigation does nothing whatsoever to enhance efficiency by, for example, redirecting funds away from litigation and toward more productive uses, and allowing key employees and decision-makers to focus their time and energy on maximizing shareholder value.[10]
- Dr. McGuire assumes investors are perfectly informed regarding, among other things, the strength of AstraZeneca's patents and the likelihood that AstraZeneca would prevail in patent litigation. Again, Dr. McGuire provides no reason to believe this is the case, particularly when the underlying patent litigation is notoriously complex, involves many

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rel. Beller v. United States, 221 F.R.D. 689, 692-95 (D.N.M. 2003) (rejecting supplemental expert report filed out of time which sought to offer opinions "broader and deeper than the opinions previously offered," and where, "in some instances, the opinions offered [were] different than the opinions contained in the [opening] report").

9 *See, e.g.*, *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 22 (2d Cir. 1996) ("Admission of expert testimony based on speculative assumptions is an abuse of discretion.") (quoted in *Seahorse Marine Supplies, Inc. v. Puerto Rico Sun Oil Co.*, 295 F.3d 68, 82 (1st Cir. 2002)).

10 Nor does it take into account that even if investors were 100% certain AstraZeneca would prevail in the Hatch-Waxman litigation, they still would value a settlement that provided early entry to Ranbaxy because it would eliminate the likelihood that, after an at-risk launch and a judgment against Ranbaxy, Ranbaxy may well be unable to afford to pay AstraZeneca the damages to which it would be entitled.

different patents, and much of the record in the case is protected against public disclosure by protective order. Of course, to the extent investors are more pessimistic about AstraZeneca's chances of prevailing than the parties to the litigation themselves are, AstraZeneca's market valuation would increase even when a settlement perfectly reflects the beliefs of the parties, rendering an event study entirely unreliable at predicting the length of supposed delay beyond the "competitive" entry date.

- Dr. McGuire assumes investors are, as a whole, perfectly rational. He simply asserts this is the case, without even considering whether investors typically overreact to news and rumors (a phenomenon confirmed by any number of analysts who—unlike Dr. McGuire—have experience and expertise in securities and finance).

* * *

This is not intended to be an exhaustive list of flaws in Dr. McGuire's analysis or his qualifications, nor could it be—without the opportunity to fully analyze and test his opinions during the expert discovery period, Defendants lack the necessary information to raise full *Daubert* and *Kumho Tire* challenges, or even effectively to cross-examine Dr. McGuire on these grounds at trial. Nevertheless, the flaws in this newly minted analysis are manifest. The Court cannot allow unreliable, speculative, and untested opinion testimony to be presented to the jury.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. McGuire's "Supplemental Declaration" of October 8, 2014, and all opinions included therein.

Dated: November 11, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Benjamin Greenblum, hereby certify that this document was electronically filed and served using the Court's ECF system on the 11th of November, 2014.

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